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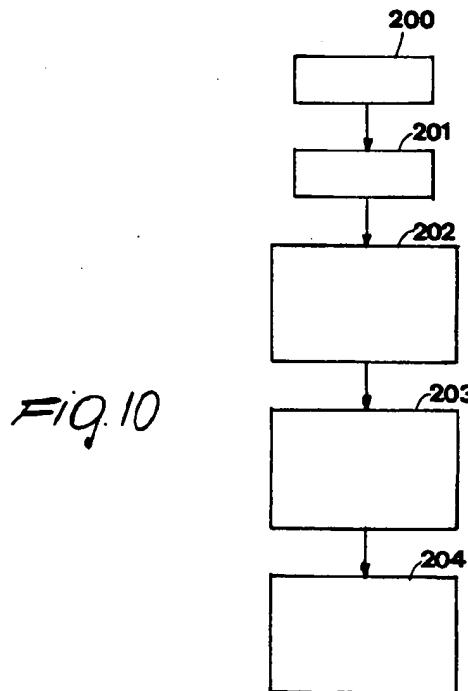
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I-38060 Volano, Trento (IT)**(54) Method for sealing containers and for ensuring their correct allocation to a preset user, and device for performing the method**

(57) A method for sealing containers and ensuring their correct allocation to a preset recipient user, which comprises: allocation of a recognition code to a user or to a service center; generation of an electronic key that is unique for the user or service center; loading or filling one or more containers of products to be transferred either from the user to a service center or from the service center to a user; sealing of the package or container by means of an electronic seal that includes an electronic locking device, in which identification data of the contained product and of the recipient and control codes are stored; transfer of the container or containers to the recipient user; execution of a recognition procedure by means of the electronic key of the recipient user, and, in case of positive outcome of the recognition procedure, authorization for access to the product in the container or containers.



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Description

The present invention relates to a method for sealing containers, in particular blood bags, test-tubes containing samples for laboratory tests and the like, and for ensuring their correct allocation to a preset user, such as a specific patient, or a specific laboratory, and to a device for performing this method.

In hospitals it is often necessary to allocate to a specific patient a type of blood or a specific blood product that has been prepared specifically for that patient.

Obviously, a mistake in allocation can cause severe harm and even the patient's death.

Human error is the most frequent cause of acute fatal hemolytic reactions in blood transfusion and may occur in procedures concerning either the taking of blood samples or the distribution and/or transfusion of blood units.

The aim of the present invention is to provide a method that can ensure a very high degree of safety, so as to in practice eliminate the occurrence of mistakes in recognizing or allocating a container intended for a preset user.

Within the scope of this aim, a specific object of the present invention is to provide a method that allows to seal the container with the possibility of memorizing and identifying or recognizing the recipient user, so as to prevent opening unless a special identification or recognition procedure that authorizes the recipient to have access to the contents has given a positive result.

Another object of the present invention is to provide a sealing device suitable for releasing, upon request, a number of information data such as the kind of test to be carried out on the contents of a container sealed by the device, laboratory test standards followed or to comply with, type of taken sample, kind of request to be satisfied or answer to be given, date, time and name of the sending forwarding operator, details on the recipient, and the like information.

Another object of the present invention is to provide a sealing device that is highly reliable, since it allows to standardize recognition procedures, frees them from subjective decisions, is relatively easy to manufacture at competitive costs, and is simple and practical to use.

According to a first aspect of the present invention, a method is provided for sealing containers and ensuring their correct allocation to a preset recipient user, said method comprising the following operating steps:

- allocating an identification or recognition code to a sending user or to a service center;
- generating an electronic key that is unique for a recipient user or service center;
- loading or filling one or more containers with product or products to be transferred either from the sending user to a service center or from the service center to the recipient user;
- sealing the package or container by means of an electronic seal that includes an electronic locking

device, in which identification data of the contained products, of the recipient user and transport instruction data are stored;

- transferring the container or containers to the recipient user;
- performing an identification or recognition procedure by means of the electronic key of the recipient user, and, in case of positive outcome of this procedure
- authorizing access to the product in the container or containers, and
- recording of information data on the followed recognition and assessment procedure.

According to another aspect of the present invention, a device for sealing containers and ensuring their correct allocation to a preset recipient user is provided and is characterized in that it comprises:

- at least one electronic seal for containers of products or materials to be allocated to the recipient user or to a service center or transport operations, said seal comprising mechanical coupling means and electronic locking means having a memory unit for said mechanical means;
- means for generating electronic keys;
- at least one electronic key that can be programmed with information data such as identification data of the recipient user;
- control means adapted to perform a comparison between data stored in said electronic locking means and data contained in the or each electronic key; and
- means for accessing and entering codes in the control means.

Further aspects and advantages of the present invention will become apparent from the following description of a currently preferred but not exclusive embodiment thereof, illustrated only by way of non-limiting example in the accompanying drawings, wherein:

figure 1 is a schematic view of a module for the electronic control of a box or container for blood transport;

figure 2 is a view of an input data module, in the form of an alphanumeric keyboard, and of a badge reader, to be connected to the module of figure 1;

figure 3 is a view of an identification or recognition device for patient test-tubes containing laboratory test samples for a patient;

figure 4 is a view of an electronic key and of a key-generating module;

figure 5 is a view of a box-like seal for transporting a container, such as a blood bag;

figure 6 is a view of an electronic locking module of a seal, such as that of figure 5;

figure 7 is a flowchart of the control software of the control module of figure 1;

figure 8 is a flowchart of the control software of the recognition device of figure 3;

figure 9 is a flowchart of the control software of the locking module of figure 6;

figure 10 shows a flowchart illustrating the general method according to the present invention; and figure 11 is a flowchart of a control software for a safety reception procedure.

A specific embodiment of a sealing device according to the present invention is described below with specific reference to bag-like containers, particularly for transporting blood and blood products.

It will be noted that the device according to the invention comprises several components that can be connected to one another and are described in greater detail hereinafter.

With reference to figures 1 to 6, a control module or apparatus 1 is schematically shown which comprises an electronic circuit 11, rechargeable batteries 12 arranged to power the circuit 11, a printer 13, and an LED 15 for indicating the ON state and the charge status of the battery 12. The control apparatus 1 also has a number of connectors, i.e., a connector 19 for connection to a battery charger (not shown), a connector 16 for connection to an electronic key 50 (figure 4), a connector 17 for connection to a box-like seal or transportation container 6 (figure 5), a connector 18 for connection to a data input module 30 and/or 35 (figure 2), and a connector 14 for connection to a key-generating module 55 (figure 4).

The control apparatus 1 is meant to check the match between the code of the recipient user, e.g. a patient, stored in an electronic key 50, and the allocation code stored in the box-like seal or transportation container 6. In case of a match, the apparatus 1 enables unlocking of the box-like seal or container 6. The control module 1 is controlled by suitable software, a flowchart of the same is shown in figure 7 and its functions will be explained hereinafter.

Figure 2 shows a data input module 30 that comprises an alphanumeric keyboard 33, a connector 31 for connection to the control module 1, and a badge reader 35 provided with a connector 36 for direct connection to the control module 1 (if the keyboard in the module 30 is missing) or for connection to a connector 32 of the module 30, in order to have both data input means available. The modules 30 and 35 are arranged to transfer the operator's personal code or other information data, which can be numeric or alphanumeric, to the control means 1.

The badge reader 35 can be of the magnetic type or of the type suitable for reading chip-cards.

Figure 3 illustrates a module 4 for identifying samples (for example test-tubes) for carrying out tests on the patient, which comprises an electronic circuit 40, a printer 44, e.g. a single-sheet printer, a connector 41 for connection to the control module 1, a connector 42 for connection to an external optical reader (not shown), a connector 43 for connection to an external module (not shown) for locking the samples (test-tubes) to be tested

in a laboratory, an internal optical reader 45, mechanical retaining means 47, for example of the clamping type for the test-tubes, and a reader 46 (located inside the module) for detecting the presence or absence of material in the test-tube held by the retaining means.

Power to the test sample identification module 4 for samples to be tested is supplied by the control module 1, to which the module 4 must be connected by means of the connector 41. The module 4 has the function of controlling the drawing of sample material (e.g. blood) from a patient, to whom an electronic personal identification key 50 has already been allotted. Once comparison between the code of the key 50 and the label on the container (test-tube) is positive, the module 4 locks the container in position by means of the clamping means 47.

After the test-tube has been filled with blood as a consequence of direct drawing from the patient, the module 4 prints a report that filling has occurred on a companion sheet and unlock the test-tube to allow its removal for being sent to a laboratory.

The operator, by using the keyboard 33, can select the type of information to be coded (e.g. on a bar code) on the container or test-tube, e.g. the kind of test to be carried out and test data requested, type of drawn sample, identification code of the operator and the like. Automatic application of date, hour, etc. can be provided, if desired.

Further information data, such as personal identification data of the patient and codes of the operations and/or functions selected by the operator can also be printed either in coded form or in alphanumeric cards on a sheet that will accompany the transportation container.

The sample identification module 4 is controlled by a specific control software, the flowchart of which is shown in figure 8 and the functions of which will be described hereinafter.

As shown in figure 4, an electronic key 50 comprises:

a connector 51 for connection to the key-generating module 55 or to the control module 1; a memory chip 52 that stores the patient's coded data, and a slit 53 for a strap (not shown) for securing the key, for example to the patient's wrist. The electronic key 50 stores a personal code of the patient, which includes for example the nosological code and the date of birth of the patient or can contain previously stored numerals for identifying a specific set (key plus sample container) to be tested.

The electronic key 50 has the function of activating the unlocking of the box-like transportation seal 7 by means of the control module 1, according to the method described hereinafter.

The key-generating module 55 is provided with a connector 59 for connection to the key 50, with an electronic circuit 57 fed by batteries 58 or by external mains through a suitable feeder, and with a connector 56 for connection to a personal computer or to the control module 1. The key-generating module 55, when connected to an electronic key 50, stores therein the personal code

of the patient, under the control of a software available in the PC or through the control module 1.

The box-like seal 6 (figure 5) is provided with a memory circuit and with connectors, i.e., a connector 61 for connecting it to the control module 1 and an additional service connector 62 for performing circuit tests with the aid of an external unit (not shown).

A solenoid 63 is arranged inside the box-like seal 6 and is arranged to mechanically lock and unlock the box 6 to allow removal of the blood or blood product from the bag that has been sealed by said seal.

The seal 6 can be released in emergency by means of screws 64. The screws 64 are arranged under a removable label (for example a metallic label) that makes it possible to detect any tampering of the box-like seal 6. The seal 6 is locked in closed position after a bag of blood or blood product, allocated to a preset patient, has been sealed inside it. Authorization to open the box-like seal 6 is given by means of the control module 1, after performing an allocation checking procedure has been performed as explained in more detail hereinafter.

The seal 6 is locked in closed position by means of the locking module 7 (figure 6), which comprises a memory circuit 71 that is powered by batteries 72 that can be recharged by means of an external battery charger (not shown) or by means of an external power supply (not shown). The connection to the battery charger or to the power supply occurs by means of an appropriate connector 74. A LED 73 is provided on the locking module 7 to indicate whether the device is ON and to indicate the charging status of the battery 72. There are also two connectors 75 and 76, one of which is used for connection to an external processing unit, not shown, such as a PC.

The seal 6 constitutes a passive electric means provided with memory circuits and with circuits for controlling the solenoid 63, in which the data for allocation to a specific patient remain stored.

The seal 6 can be controlled by the locking module 7 by means of a PC that is provided with a suitable control software, the flowchart of which is shown in figure 9 and the functions of which will be described hereinafter.

The operation of the above described sealing device is as follows:

In a ward, a preset patient code, for example a patient's nosological code including date of birth, etc., is generated by means of the key-generating module 55 and is stored in an electronic key 50 that can be physically allocated to the patient, for example by applying it to his wrist by means of a strap of self-sealing type.

If required, the device then prints patient's identification labels, unit requests with the identification data of the patient, any specific activity to be performed on the sample, etc..

A blood or blood product supply center, after receiving a request for allocation of a bag of blood for a given patient, identifies a bag of blood or blood product that has the requested properties.

Sealing of the bag is then performed with the electronic box-like seal 6, while said seal is connected to the locking module 7 through the respective connectors 61 and 75. The module 7 can be connected to an external processing unit (not shown) via its connector 76. The locking module 7, by energizing the solenoid 63, causes locking of the seal 6 and stores the unlocking code (that is to say, the bag code, the recipient code, and the control code) in the seal 6 which is now secured to or around the bag. The bag thus sealed is forwarded to the patient, for example delivered to the ward in which the patient is hospitalized.

The control of this function is performed in the software of the external processing unit, e.g. a PC, and by the software inside the locking module 7, which will be described in greater detail hereinafter with reference to figure 9.

The product code is first entered in the external processing unit (step 120) which reads out any stored data (step 120A) and stores the read out data either into a file (stage 120B) and/or into the memory of a module 1 (stage 120C). The processing unit effects then the necessary comparisons (step 120D) and after that the code of the recipient user (patient) (step 121) is entered. If provided for, the operator code is entered (step 122) by means of the entry module 30 and/or 35. Subsequently the control code for mutually checking the product code and the recipient user (patient) code, generated in the module 7 and meant to be transferred into the seal 6 (step 123), is generated. The previous code and the data stored in the memory of the seal 6 are read (step 124) and stored in an appropriate external history file (for example on a PC) (step 125). If required, information for a recipient laboratory or other identification data concerning the forwarding center or control data can be stored (step 126A). In step 126 the box-like seal 6 is locked by energizing the closure solenoid 63 (figure 5). The codes previously generated by the locking module 7 are then recorded in the seal 6 (step 127) and re-read in step 128. If the comparison (step 129) is positive, the codes are stored in an external input history file (step 130) and the process ends by restoring the routine (step 131). If the comparison is negative, the locking module 7 unlocks the seal 6 and requests the entire procedure to be repeated (step 132).

In the ward, the comparison between the code of the electronic key 50 and the codes contained in the electronic box-like transportation seal 6 is performed by means of the control module 1.

If the comparison is positive, the control module 1 authorizes the opening of the box-like seal 6, thus allowing to use the contents of the bag.

Otherwise, unlocking does not occur and the seal cannot be opened. It is also possible to provide for an emergency opening of the bag. In any case, appropriate messages are printed by means of the printing machine or printer 13, as described hereinafter with reference to figure 7.

More particularly, the control module 1 is switched on (step 100) and the circuit between the electronic key 50 and the box-like seal 6 is closed by means of the respective connectors 16 and 17 (figure 1).

If provided for, the operator code is entered (step 101) by means of the entry module 30 and/or 35; if said code is recognized, the user code is read in the electronic key 50 (step 102), then both the product code and the user code are read in the electronic seal 6, where the control code "X" is also read (step 103). A control code "Y" is generated in the subsequent step 104 from the product code read in the seal 6 and from the code read in the electronic key of the patient; then a comparison between these control codes "X" and "Y" is performed in the subsequent step 105. Directly after this (step 106), the date and time are read in the suitably provided clock in the control module 1. The step 107 shows the three possibilities that arise from the comparison in step 104.

If the control codes "X" and "Y" are identical, the allocation is correct, and therefore a message containing a report of normal opening, the date, the time, the product code, the user code in the seal 6, and the code of the electronic key of the patient is printed in step 108, and a signal authorizing the opening of the box-like seal 6 is generated in the subsequent step 109, whereas during the subsequent step 110 said codes and the operator code are stored in the memory of the seal 6 or in the key 50, and the operation ends (step 111).

If the control codes "X" and "Y" differ, this means that the allocation is incorrect, and therefore a message that contains the indication of an error in recipient user code and date, time, product code, sending user code in the seal 6, and the code of the electronic key of the patient is printed in step 112. The history data of the event are stored in the seal 6 or in the key 50 in step 113, and the operation ends (step 114).

If the control codes "X" and "Y" are different but the code of the key has a preset emergency value, the emergency opening status is recognized. A message that contains the emergency opening indication, date, time, product code, user code in the seal, code of the electronic key, and code and identification data of the key owned by the person in charge, is printed in step 115. The box-like seal 6 is then opened in step 116 and the said codes and the operator code are stored in said module in step 117.

The operation ends in the subsequent step 118, where the control module 1 is switched off, as in steps 111 and 114.

At a center where empty and incorrectly allocated containers or bags are gathered, the container code is read and the device is unlocked (step 111A) and if printing out of such code is required, this is done at 111B. Then, all information data are memorized (step 111C) and/or stored in a file in an external PC at step 111D and checked.

A way in which the control module 1 and the module 4 can be used for identifying samples of material to be subjected to chemical analysis is described hereinafter.

For convenience, reference is made to the requirements of a hospital ward with respect to a laboratory or transfusion center.

Blood samples, drawn in the ward from a specific patient, are to be delivered to a transfusion center for analysis. Also in this case it is necessary to guarantee accurate identification of the blood sample that belongs to a given patient. As explained above, it is necessary to prepare beforehand a key 50 for identifying the patient and a test-tube labelled with the same code.

Should the comparison between the code of the key 50 owned by the patient and the label on the container be positive, the empty container is fixed by means of the retaining means 47 and the comparison result is printed on the label of the container. Only after the container has been filled as a consequence of a blood drawing from the patient, the container is released for being forwarded to the transfusion center.

This process is controlled by the software (see flowchart of figure 8) of the module 4 for identifying samples of blood or of other material to be analyzed, whose functions are as follows.

The identification module 4 is switched on (steps 139 and 140) by means of the connection of the electronic key 50 and of the container of the material to the control module 1. If provided for, the entry module 30 and/or 35 is used to enter the code of the operator (step 141); only if said code is identified, the code of the electronic key 50 is read (step 142).

A check operation for spotting errors and in particular for making sure that the test tube is the correct one is effected at step 142A. Should the test tube be a wrong one, a further check operation is performed at step 142B to determine whether identification code of the ward or laboratory is stored in the key 50. If yes, then such a code is digitized in the key 50 (step 142) and memorized; if not, or after storing of the code, information data available in the key are displayed and/or printed at step 142D.

At stage 143 a number of assessments are automatically performed, i.e. without intervention of the operator, on the blood sample, e.g. the kind of test required, identification of the laboratory responsible for carrying out the test, details on the laboratory tests, modalities of blood taking, amount of blood required for the test, conditions for transporting the sample, type of answer, etc.. A check for errors is made at stage 143A, whereas at step 143, the internal optical reader is used to read the code of the container of the material (for example test-tube), and other desirable information data and in step 144 a comparison is made between the code of the electronic key 50 and the code of the pre-labeled test-tube.

If the comparison fails, a message containing an error indication, the date, the time, the code of the user key, the code of the container, and the code of the operator (step 145) is printed on the label of the test-tube, and the process ends.

If the comparison is positive, the container is blocked by the retaining means 47 (step 146) of the module 4 for identifying the samples of material. The reader 46 then

checks for the presence of material in the container (step 147), and if there is liquid or other material in it the date and time are read in step 148.

At step 149 printing is performed on the label of the container, e.g. indicating the date, the time, the code of the container, the code of the recipient user, and optionally the code of the operator and the required tests on sample. Checking is performed to spot errors at stage 149A, for punching document at stage 149B, for updating information data on the key 50 at stage 149C, whereas data storing in the key is effected at step 149D.

At step 150, the container is then released, and the date, the time, the code of the electronic key, and the code of the container are printed on the companion request form. After storing in an appropriate file in the control module 1 (step 151), the process ends.

The above described method makes it possible to ensure correct identification of samples of material to be tested that originate from a well identified patient, with the possibility of reporting on any identification errors by printing appropriate messages, on the whole file history of both the container, its contents and the sample in the test tube.

The labels used to identify the various containers can have bar codes that can be read with optical readers preset for bar codes.

Figure 10 diagrammatically illustrates the main sequence of events according to the method of the present invention.

First of all, the sending user or operator and a recipient user or laboratory are identified by a specific code, that is also stored in an electronic key (step 200). Then, identification data of a container and the material (e.g. blood) to be filled in the container and transferred and any treatment operation to be sequentially performed on the material are memorized on an electronic seal for the container at step 201.

At step 202 the container is filled or loaded, sealed by means of an electronic seal and delivered to a recipient user or laboratory. A recognition procedure designed to check the information data concerning the operator responsible for the transportation, date, hour, place of delivery, etc., is carried out at step 203 by making use of the memorized electronic key, whereas unlocking of the container and access to the material contained in it is performed on step 201.

Should the container be delivered to a laboratory or service center, an automatic safety reception procedure can be performed as illustrated in figure 11.

The code of the transportation operator is checked at step 205. The (bar) code on a test tube 47 accompanying the container is read out at step 206 and information as to place, date, hour, receiving operator code, etc., are added to the label at step 207. The whole bulk of such added information data is stored in a memory at step 208 and at step 209 the same information data are printed out on a sheet and placed on a fil (step 210).

At step 211, the container, if empty, is stored in a storeroom for subsequent utilization, or forwarded to a processing unit, e.g. testing unit, or filling unit.

The device according to the invention is susceptible of numerous modifications and variations within the scope of the invention.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

15 Claims

1. Method for sealing containers and ensuring their correct allocation to a preset recipient user, characterized in that it comprises the following operating steps:

- allocating an identification or recognition code to a sending user or to a service center;
- generating an electronic key that is unique for a user recipient or service center;
- loading or filling one or more containers with product or products to be transferred either from the sending user to a service center or from the service center to the recipient user;
- sealing the package or container by means of an electronic seal that includes an electronic locking device, in which identification data of the contained product(s) of the recipient user and control codes are stored;
- transferring the container or containers to the recipient user;
- performing an identification or recognition procedure by means of the electronic key of the recipient user, and, in case of positive outcome of this procedure;
- authorizing access to the product in the container or containers; and
- recording of information data on the identification and assessment procedures followed.

2. Method according to claim 1, characterized in that said loading or filling comprises identification by means of a control device of the electronic key and of a service container, both of which are pre-coded,

- comparison of the data of the service container with those of the electronic key;
- printing of the data concerning the outcome of the comparison and consequent validation or invalidation of the container;
- securing of the container so as to fix it to the control device before loading;
- loading or filling of the container; and

- printing of data related to the outcome of the operation.
3. Method according to claim 2, characterized in that said loading or filling operation comprises:
- reading the container content code by means of an external processing unit;
 - entering the code of the recipient user;
 - activating a sealing procedure by means of locking means that are provided with memory unit allowing bidirectional transfer of codes and data and creation of control codes, and
 - sealing of the container by means of electronic sealing means.
4. Method according to any one of the preceding claims, characterized in that said recognition or identification procedure comprises:
- reading the data of the container by means of the control device;
 - comparing the read data with the data of an electronic key of the recipient user;
 - printing the data obtained from the outcome of the comparison and consequent authorization to or prevention from opening the electronic seal; and
 - storage of the operation outcome data.
5. Method according to claim 4, characterized in that it comprises entering operator code in the control device.
6. Method according to any one of the preceding claims, characterized in that in case of identification failure following the recognition procedure, a procedure for emergency unlocking of the electronic seal is followed.
7. Device for sealing containers and ensuring their correct allocation of to a preset recipient user, characterized in that it comprises:
- at least one electronic seal for containers of a product(s) or material(s) to be allocated to the recipient user or to a service center or transportation operator, said seal comprising mechanical coupling means and electronic locking means having a memory unit for said mechanical means;
 - means for generating electronic keys;
 - at least one electronic key that can be programmed with information data such as identification data of the recipient user;
 - control means that are adapted to perform a comparison between data stored in said electronic locking means and data contained in the or each electronic key; and
- means for accessing and entering codes in the control means.
8. Device according to claim 7, characterized in that said code entry and access means comprise an alphanumeric keyboard.
9. Device according to claim 8, characterized in that said code entry and access means comprise a badge reader.
10. Device according to any one of claims 7 to 9, characterized in that said electronic seal comprises an actuation solenoid.
11. Device according to claim 10, characterized in that said electronic seal comprises a box-like body that can be opened and closed for receiving mechanical locking means and electronic blocking means.
12. Device according to claim 10 or 11, characterized in that it comprises a processing unit that can be connected to said electronic blocking means.
13. Device according to any one of claims 7 to 12, characterized in that said control means comprise at least one printer.
14. Device according to any one of claims 7 to 13, characterized in that it comprises means for identification of containers for the material to be analyzed, said means including at least one reader for reading data available on the container, means for comparing the data read on the container and the data stored in an electronic key, and a printer for printing the data of the comparison.

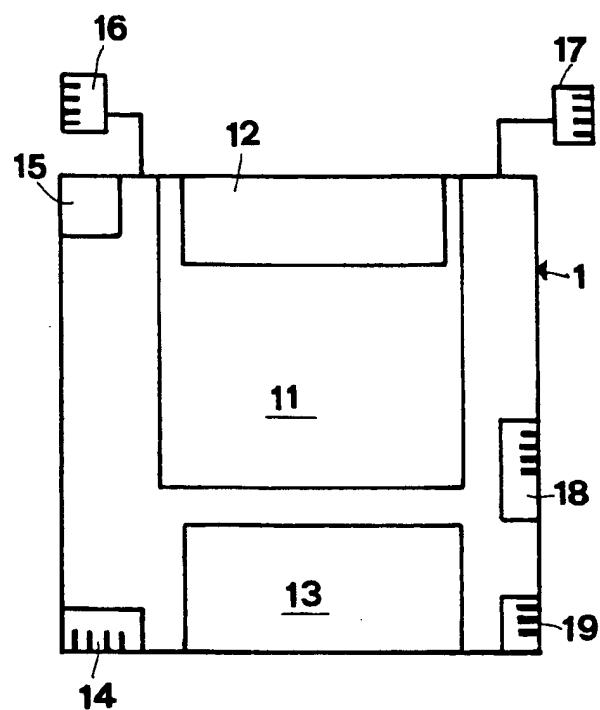
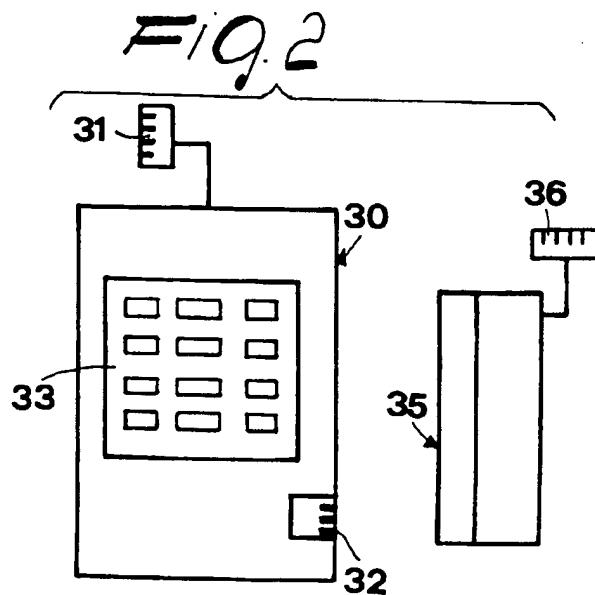


FIG. 1



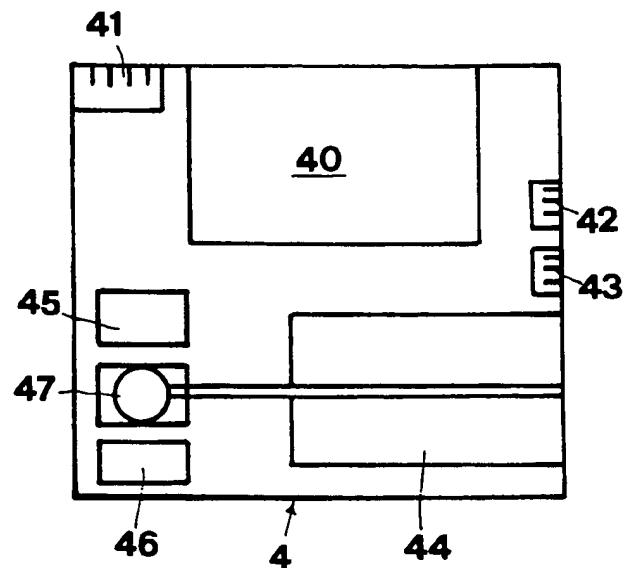


Fig. 3

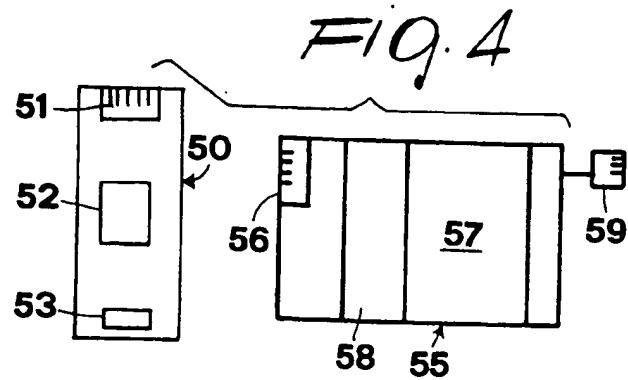


Fig. 4

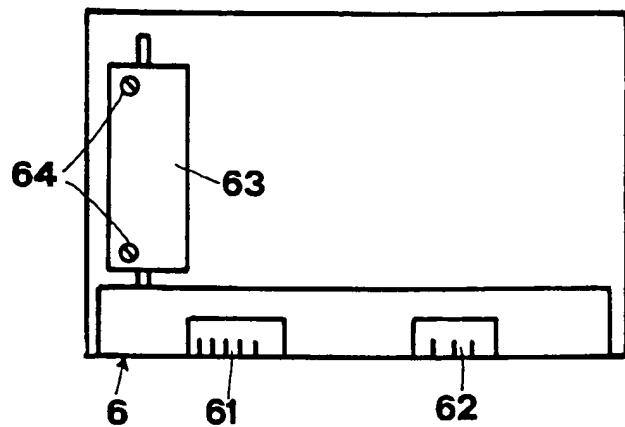


Fig. 5

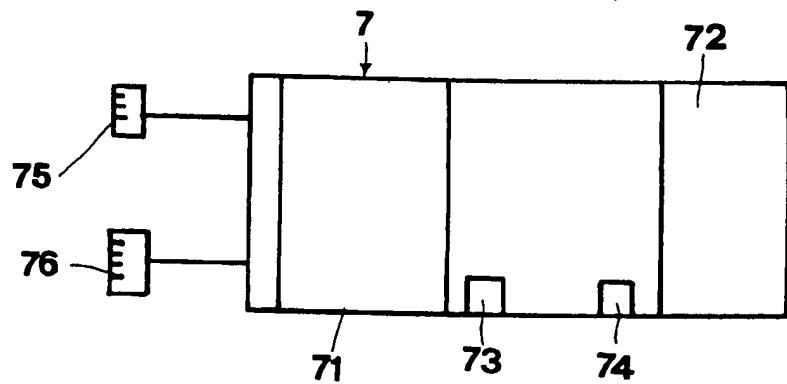


Fig. 6

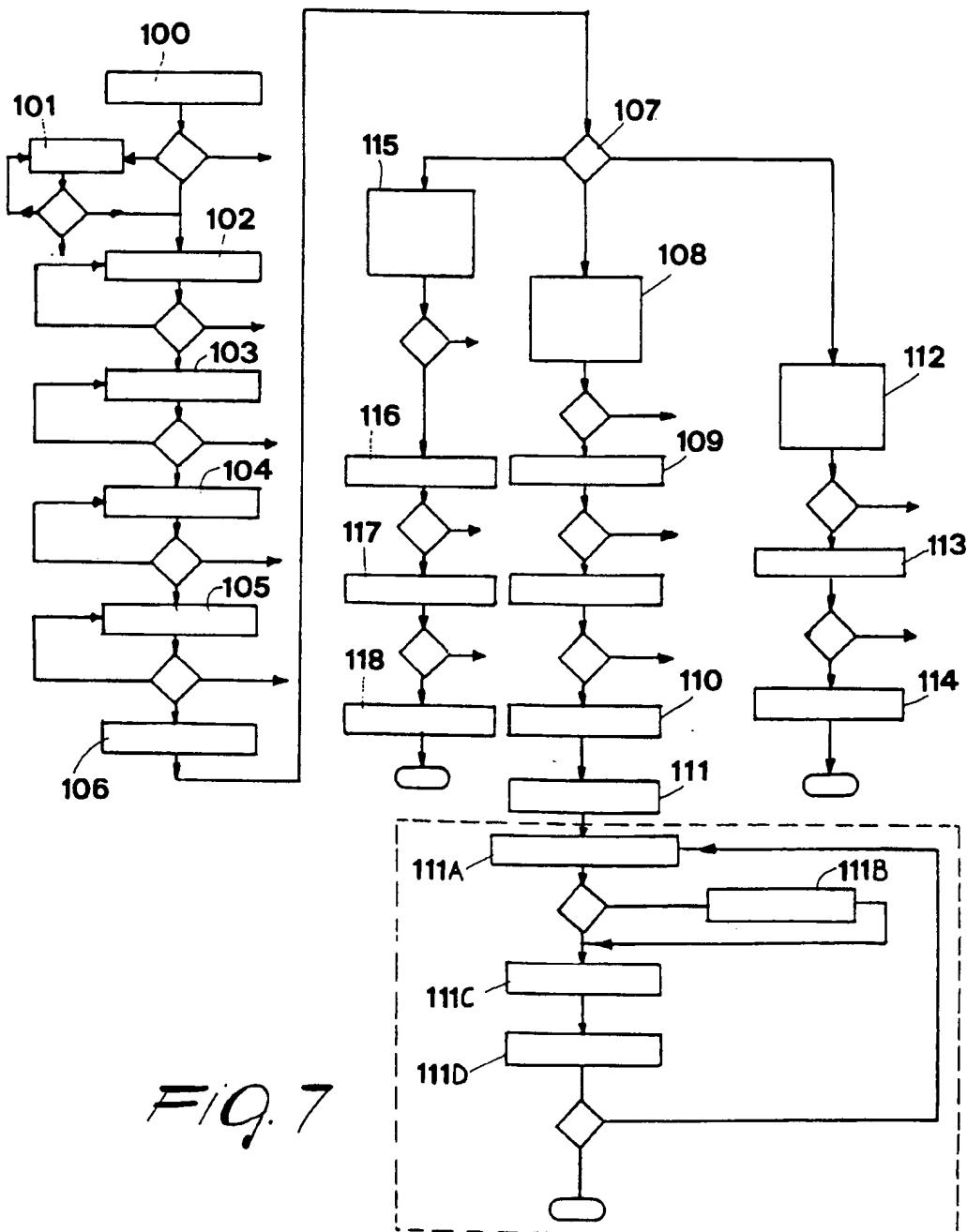
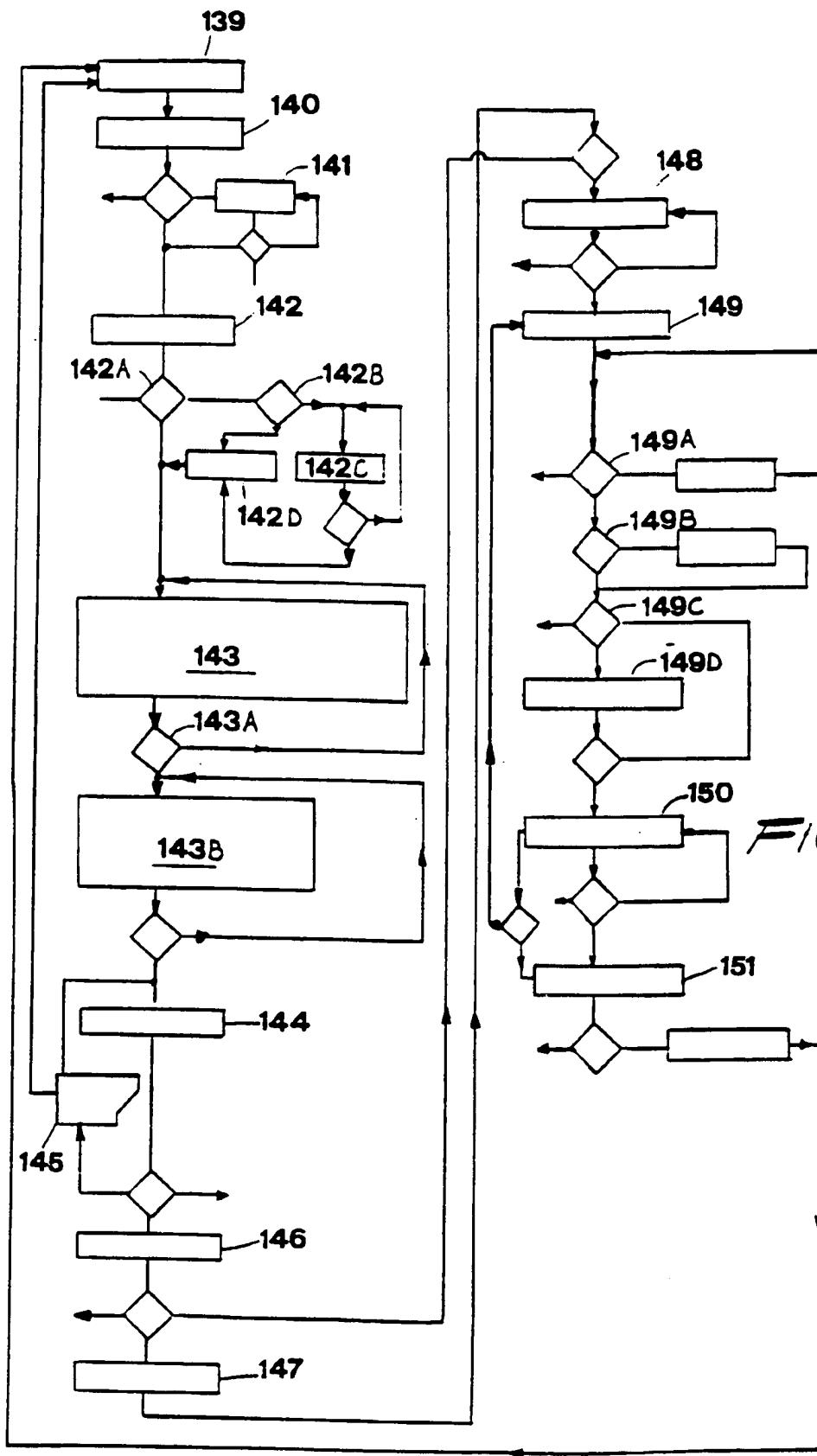


FIG. 7



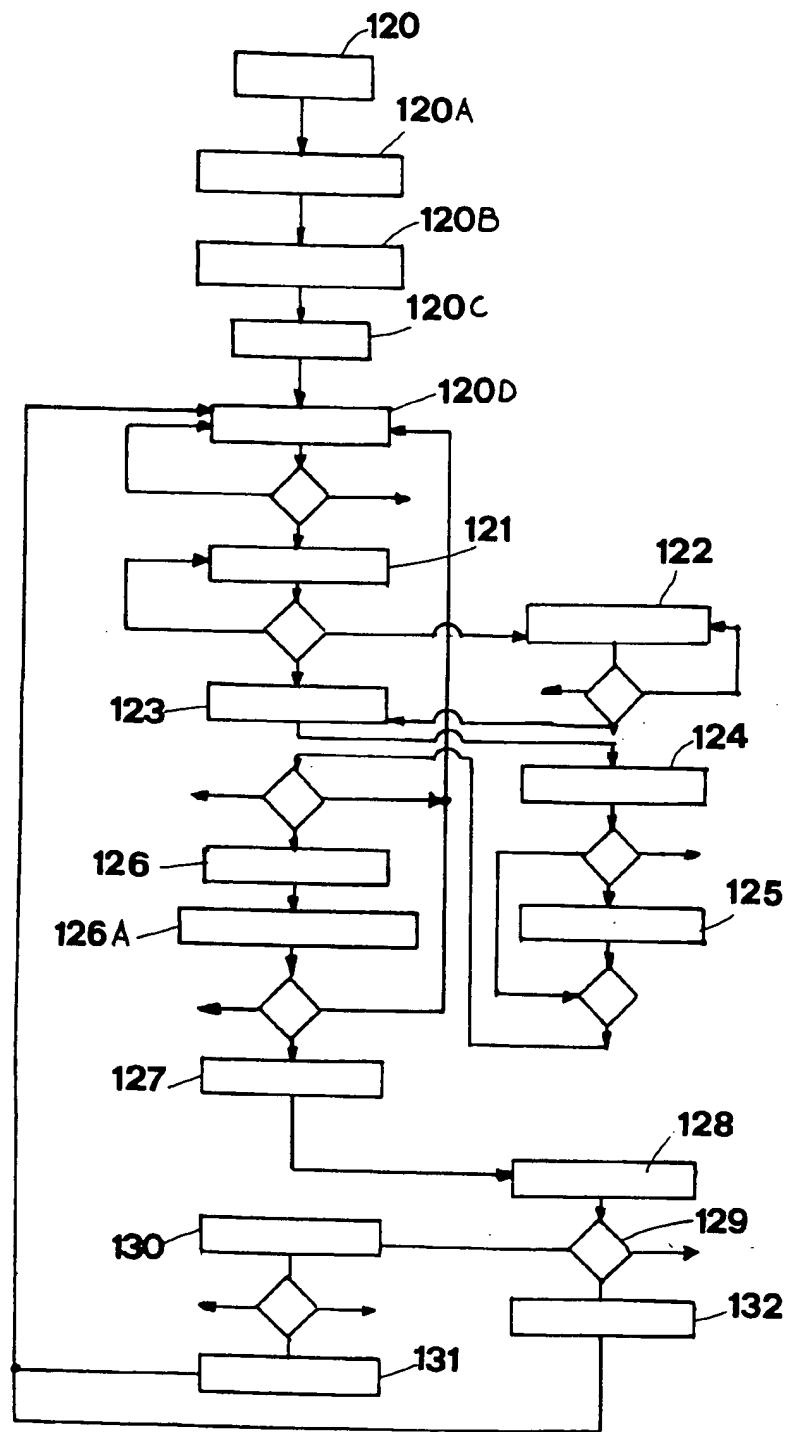
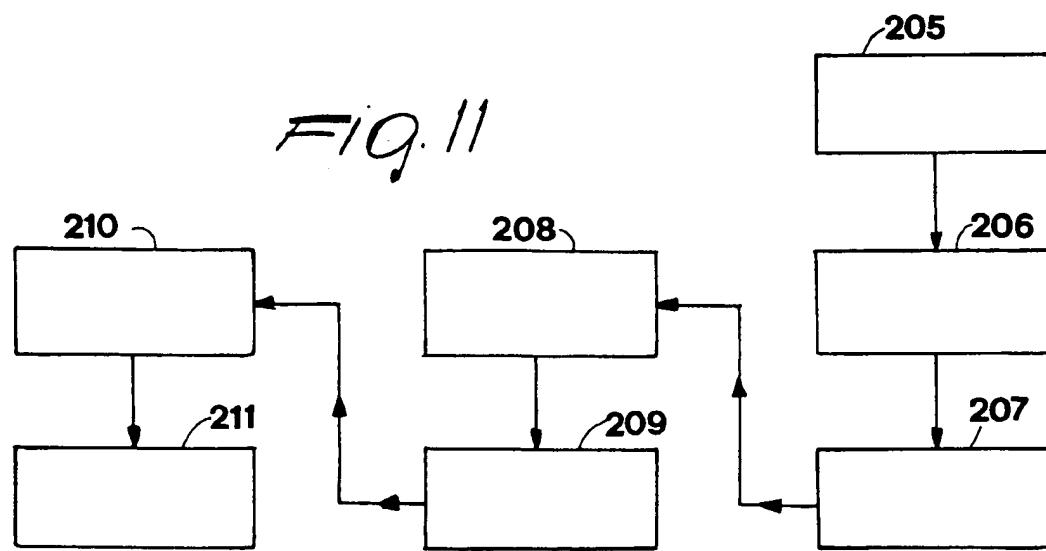
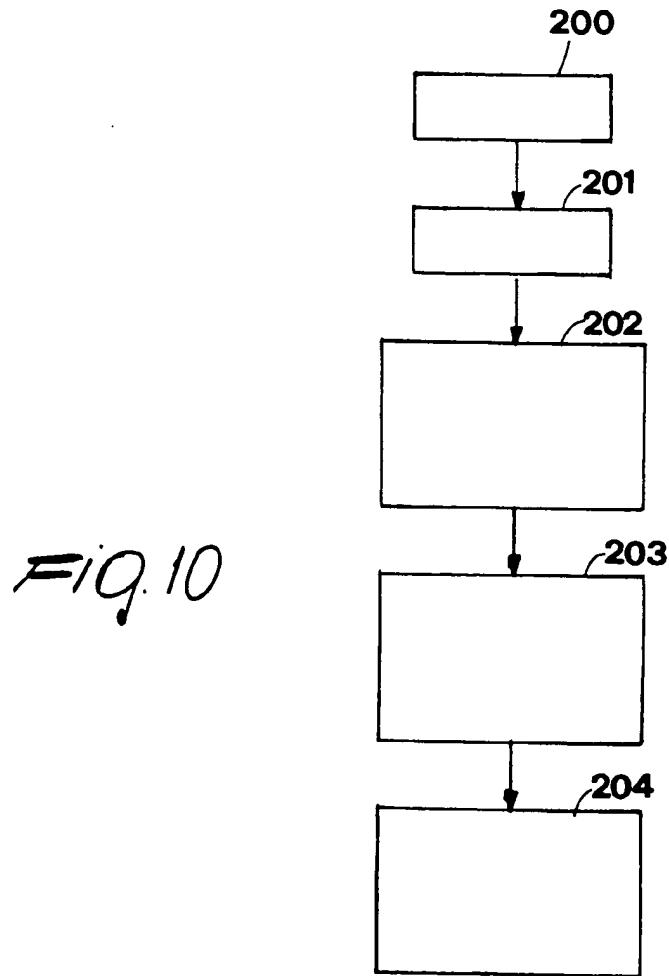


Fig. 9





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 10 9624

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